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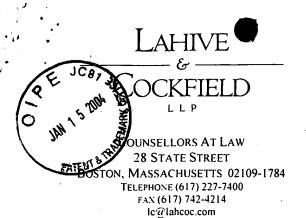
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Assistant Commissioner for Patents Washington, D.C. 20231

Re:

U.S. Patent Application No.: 09/469,637

Non-Invasive Enzyme Screen for Tissue Remodelling-Associated

Conditions

Inventors: Moses et al. Filed: December 22, 1999 Our Ref. No.: CMZ-083CPCN

Dear Sir:

I enclose herewith for filing in the above-identified application the following:

- 1. Information Disclosure Statement;
- 2. PTO Form 1449; and
- 3. Return receipt postcard.

No additional costs are believed to be due in connection with the filing of this Information Disclosure Statement. However, please charge any other necessary fees due in connection with the enclosed statement to our Deposit Order Account No. 12-0080. For this purpose, a duplicate of this sheet is attached.

I hereby certify that this correspondence is deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents. Washington. D.C. 20231 on:
218.00
Date
Elizabeth A. Hanley. Registration No. 33,505

Respectfully submitted,
LAHIVE & COCKFIELD, LLP

Elizabeth A. Hanley Registration No. 33,505 Attorney for Applicants



Office No. CMZ-083CPCN

THE "RECEIVED" STAMP OF THE PATENT AND TRADEMARK OFFICE IMPRINTED HEREON ACKNOWLEDGES THE FILING OF:

Description of Paper*: Transmittal Letter (in duplicate) (2 pages), Information Disclosure Statement (2 pages), PTO Form 1449 (3 pages), and this return receipt postcard.

Title: Non-Invasive Enzyme Screen for Tissue Remodelling-Associated Conditions

Name of Applicants: Moses et al.

Serial No.: 09/469,637

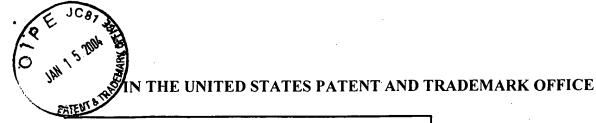
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In re the application of: Marsha A. Moses, Michael

R. Freeman and Dmitri Wiederschain

Serial No.: 09/469,637

Filed: December 22, 1999

For: NON-INVASIVE ENZYME SCREEN FOR

TISSUE REMODELLING-ASSOCIATED

CONDITIONS

Attorney Docket No.: CMZ-083CPCN

Assistant Commissioner For Patents Washington, D.C. 20231

Group Art Unit: N/A

Examiner: N/A

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By:

Elizabeth A. Hanley Reg. No. 33,505

Assistant Commissioner for Patents Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Applicant and their attorney are aware of the publications and information listed on the attached PTO Forms 1449, and in accordance with 37 C.F.R. §1.97 hereby submit these publications for the Examiner's consideration. In accordance with 37 C.F.R. § 1.98(d), no copies of the publications are enclosed. This Disclosure Statement presents publications that are of record in U.S. Application No. 08/843,095

- 2 - Group Art Unit: N/A

Serial No.: 09/469,63

of which this application is a continuation application. Copies of any publication cited herein will be provided upon request.

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, the Applicant understands the Examiner will make an independent evaluation of the cited publications.

Under 37 C.F.R. § 1.97(b)(3), no additional costs are believed to be due in connection with the filing of this disclosure. If, however, a first Office Action on the merits issues in this application bearing a mailing date prior to the date of this Information Disclosure Statement, please charge the appropriate fee as required under 37 CFR 1.17(p) to our Deposit Order Account No. 12-0080.

Respectfully submitted,

LAHIVE & COCKFIELD, LLP

Elizabeth A. Hanley Registration No. 33,505 Attorney for Applicant

28 State Street Boston, MA 02109 (617) 227-7400 Date:

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LIST	OF	PUBLICATIONS	CITED B'	Y APPLICANT ssary)	APPLICANT Marsha A. Mose	es et al.			
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	- AA	5,270,447	12/93	Liotta et al.					
	AB	5,324,634	06/94	Zucker		435	7.23	·	
	AC	5,344,760	09/94	Harvey et al.			7.5		
	AD	5,482,848	01/96	Dickson et al.			219		
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	AF	691 409	10/96	EPO					
	AG	WO 90/10228	09/90	PCT EPO PCT					
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-		OTHERS	Cincludina	n Author Title Da	te, Pertinent Pages	s Etc.)			
	AN	Attallah, A. et	al.,"Com	parative Study Bet	ween Cytology and	Dot-ELIS	SA for Early I	Detection	ı of
	AO	Basta M. et a	ncer", A.J.C.P., Vol. 102, No. 1, pp. 109-114 (1996); t al.,"Cytokeratin Shedding in Urine: A Biological Marker for Bladder Cancer?", <i>British</i>						
	ΑP		Journal of Urology, Vol. 61, pp. 116-121 (1988); Blaser, J. et al.,"A Sandwich Enzyme Immunoassay for the Determination of Neutrophil Lipocalin						
			n Body Fluids", <i>Clinica Chimica Acta</i> , Vol. 235, pp. 137-145 (1995);						
	AQ				tate-Specific Antig				
				c Carcinoma and Benign Prostatic Hyperplasia", <i>Scand: J. Urology Nephrol</i> 97-103 (1991);					pnroi.
	AR	Braunhut, S.	et al., "Re	tinoids Modulate E	ndothelial Cell Pro				
		Proteases an Vol. 259 (18):			oproteinases (TIMI	P)", <i>Journa</i>	al of Biologic	al Chem	istry,
	AS				in Urine", Eur. Uro	<i>I.</i> , Vol. 26,	pp 18-21 (1	994);	
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5 2004		FILING DATE	GROUP	
18H / 1		April 25, 1997		

OTHERS (including Author, Title, Date, Pertinent Pages, Etc.) Carr, M. et al., "Urinary Levels of the Renal Tubular Enzyme N-Acetyl-β-D-Glucosaminidase in Unilateral Obstructive Uropathy", The Journal of Urology, Vol. 151, pp. 442-445 (1994); Fernandez-Luna, J. et al., "Measurement of Protein HC (α1 microglobulin) and protein HC-IqA complex in different body fluids", J. Clin. Pathol., Vol. 41, pp. 1176-1179 (1988); Fine, R., et al., "Accumulation of Urinary Cancer-related Glycoprotein, EDCI, in Psoriasis", Journal of Investigative Dermatology, Vol. 73, pp. 264-265 (1979); BD Garnick, M., "Prostate Cancer: Screening, Diagnosis, and Management", Annals of Internal Medicine, Vol. 118, pp. 804-818 (1993); Garnick, M., "The Dilemmas of Prostate Cancer", Scientific American, Vol. 270 (4), pp. 72-81 BF Grover, P. et al., "Analysis of Prostatic Fluid: Evidence for the Presence of a Prospective Marker for Prostatic Cancer", The Prostate, Vol. 26, pp. 12-18 (1995); BG Ho, K. et al., "Urinary Beta-Glucuronidase Activity as an Initial Screening Test for Urinary tract Malignancy in High Risk Patients", Cancer, Vol. 76, No. 3, pp. 473-478 (1995); Jones, A. et al., "Urinary N-acetyl-β-glucosaminidase Activity in Type I Diabetes Mellitus", Ann Clin Biochem, Vol. 32, pp. 58-62 (1995); Kossakowska, A. et al., "Tissue Inhibitor of Metalloproteinases-1 (TIMP-1) RNA Is Expressed at BI Elevated Levels in Malignant Non-Hodgkin's Lymphomas", Blood, Vol. 77 (11), pp. 2475-2481 Lee, M. et al., "Analysis of Affinity and Structural Selectivity in the Binding of Proteins to Glycosaminoglycans: Development of a Sensitive Electrophoretic Approach", Biochemistry, Vol. 88, pp. 2768-2772 (1991); ВК Liotta, L. et al., "Cancer Metastasis and Angiogenesis: An Imbalance of Positive and Negative Regulation", Cell, Vol. 64, pp. 327-336 (1991); Lu, X. ET AL., "Immunological Quantitation of Levels of Tissue Inhibitor of Metalloprteinase-1 in Human Colon Cancer", Cancer Research, Vol. 51, pp. 6231-6235 (1991); Margulies, I. et al. "Urinary Type IV Collagenase: Elevated Levels Are Associated with Bladder Transitional Cell Carcinoma" Cancer Epidemiology, Biomarkers & Prevention, Vol. 1, pp. 467-474 (1992): BN Miller, D. et al., "Purification and Characterization of Active Human Interleukin 1β-converting Enzyme from THP.1 Monocytic Cells", Journal of Biological Chemistry, Vol. 268 (24), pp. 18062-18069 (1993); Moses, M. et al., "Production of Matrix Metallorproteinases and a Metalloproteinase Inhibitor by BO Swarm Rat Chondrosarcoma", Biochemical and Biophysical Research Communications, Vol. 199 (1), pp. 418-424 (1994); Date Considered Examiner

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LIST OF PUBLICATIONS CITED BY APPLICANT (Use several sheets if necessary)

Marsha A. Moses et al.

April 25, 1997

OTHERS (including Author, Title, Date, Pertinent Pages, Etc.) Paigen, B. et al., "Urinary Glucuronidase and Arylsulfatases in Identical Twins of Bladder Cancer Patients", Cancer Research, Vol. 44, pp. 3624-3626 (1984); Robins, S. et al., "Direct, Enzyme-Linked Immunoassay for Urinary Deoxypyridinoline as a Specific Marker for Measuring Bone Resorption", Journal of Bone and Mineral Research, Vol. 9, No. 10, pp. 1643-1649 (1994); Schmitt, M. et al., "Tumor-Associated Urokinase-Type Plasminogen Activator: Biological and Clinical Significance", Biol. Chem., Vol. 373, pp. 611-622 (1992); Tetzner, E. et al., "Osterreichische Zeitschrift fur Erforschung and Bekampfung der Krebskrankheit", Osterr. Zschr. Krebsforsch., pp. 233-237 (1971) -(English Abstract Included); Tomita, Y. et al. "Immunohistochemical Detection of Intercellular Adhesion Molecule-1 (ICAM-1) CE and Major Histocompatibility Complex Class I Antigens in Seminoma", Journal of Urology, Vol. 149, pp. 659-663 (1993); Woessner, J., "The Family of Matrix Metalloproteinases" Annals New York Academy of Sciences, Vol. 732, 11-21 (1994). Date Considered Examiner

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